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TITLE: The Role of Dietary Fat and Antioxidant in Prostate  
Cancer Risk Among West African Migrants in America: A  
Pilot Case-Control Study

PRINCIPAL INVESTIGATOR: Flora A. Ukoli, MB, BS, MPH

CONTRACTING ORGANIZATION: Howard University Cancer Center  
Washington, DC 20060

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<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> Howard University Cancer Center Washington, DC 20060  E-Mail: <a href="mailto:fukoli@howard.edu">fukoli@howard.edu</a>			<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
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<b>13. ABSTRACT (Maximum 200 Words)</b>  78 African migrants resident in Washington metropolitan area were registered to participate in the study and 48 completed the study. Their ages ranged from 40 - 65. 85% live in Maryland, 10% in Washington DC and 5% in Virginia. 57% are from Nigeria, 26% from Ghana, 9% from Cameroun and 4% each from Liberia and Ethiopia. 2 persons did not state their income. About one third earn over \$75,000, just over a third earned above \$30,000 and less than a third earned less than \$30,000 annually. Of the 48 persons who completed the survey only two had abnormal PSA over 4.00ng/ml. So far the other cases of prostate cancer identified have not come forward for the study. However fatty acid analysis has been completed for a subset of the study population. In comparison with the Nigerian population from a rural community there is no difference in total fatty acid levels, 2,318 vs. 2,096. The fatty acids that have been found to be higher among the migrant populations are mainly the omega-6-fatty acids, while the omega-3-fatty acids are higher among the Nigerian sample.				
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## **INTRODUCTION:**

This pilot study targeted African migrants in the Washington metropolitan area is first of its kind in this population and is focused on men 40 years and older. The main objective was to locate prostate cancer cases and select community based controls matched for age and country of origin such that both groups will be compared with relation to their dietary risk factors for prostate cancer. The specific nutrients of interest are vitamin E and essential fatty acids. Food items of interest include dairy, dietary supplements, fruits, vegetables, meat and fish.

## **STATEMENT OF WORK:**

### **Task I      Start-Up Phase and Plan Development (1 – 2 months)**

#### Locating Urologists who have West African prostate cancer patients:

A letter of introduction using a mailing list obtained from the Association of Urologists was used to contact all the urologists in this area. Since they had no way of knowing if a black patient was from Africa they were requested to post the study flyer in their office such that interested patients can contact the PI. Some urologists responded to this letter and promised to inform their eligible patients. Only a select sample of urologists were contacted a second time by telephone with the intention of stimulating more interest in the study.

#### Development of study instruments.

The study instrument was developed and tested on an initial 10 participants who suggested additional food items. All participants completed a 24-hour dietary recall, a 172-item food frequency questionnaire (FFQ) and a dietary questionnaire on their use of dietary fat. The FFQ is made up of 9 meat/fish, 12 carbohydrate, 12 vegetable and 8 fruit sub-groups in addition to sub-groups for nuts, spices, vitamin/supplements, drinks, dairy, cakes/dessert and candy/chocolates. Crude food models were developed for this study by the PI to assist participants to select serving sizes of various food items. An artist or a photographer will be approached to develop realistic pictures or paintings of serving sizes, which ever is cheaper.

#### Contacting West African Associations, Churches, Mosques and International food stores:

A list of community based associations, churches and African embassies has been started and will continue to be updated. Leaders or representatives of the churches and associations identified and owners of international food stores were contacted by mail followed by a telephone call to solicit their cooperation by asking them to distribute flyers to their members or to display study flyers in their facility.

### **Task II      Subject Recruitment and Data Collection (2 – 10 months)**

#### Prostate cancer screening for men 40 years and older.

The Howard University Cancer Center has conducted prostate cancer screening monthly over the past 24 months with widely disseminated media public announcement and distribution of flyers. Four of these screenings were at health fairs located in Washington DC; The NBC4 Fitness (2000 and 2001) and Health Expo and the Mazique Community Health fair (2000 and 2001). The public is adequately informed that they do not require health insurance for this screening both on the flyer and on all public service announcements on radio and television. Flyers about the study and about the screening were distributed at a health conference organized by the African Solidarity Association in DC, and the PI had an opportunity to talk about the study at this conference.

Identification and recruitment of cases and matched controls into the study.

111 men have been registered of whom 55 have completed the study questionnaires (demographic, anthropometric and dietary information) Urine samples have been collected and the blood samples centrifuged such that the blood clot, cells, serum and plasma are all stored at -70 degrees in labeled microvials at the Howard University Cancer Center. So far all PSA estimates have been completed and essential fatty acid analysis has been completed for 12 participants. There has been no attempt at matching controls to cases at this point.

A total of 14 people with abnormal PSA have been identified from the following sources:

Howard University Cancer Center registry	3
HUCC prostate cancer-screening program	5
Study participants	6

Medical, dietary and other epidemiological data collection from cases and controls.

Only 5 of the prostate cancer cases have completed the study protocol, one of the register who also attended the screening program, and 4 from among study participants. All 5 identified from screening, 2 from the registry and 2 study participants are yet to complete the study protocol. No medical record information has been collected from any case. 45 normal controls 40 years and older have completed the study protocol.

Laboratory analysis.

	<u>No Analyzed</u>
PSA	111
Essential FA	12
Lipids	12
Testosterone	12
Vitamin E	11
Vitamin C	7
Selenium	6

**Task III Interim Data Analysis (3 – 11 months)**

Study SPSS Database:

All epidemiological data of the 111 persons have been entered into two data sets, one SPSS database for those who completed all study protocol and a second database for those who only attended the prostate cancer screening activity. The laboratory data has been entered into a separate SPSS database and has not been merged with the epidemiological data.

Dietary Assessment database (NUT VI program)

The FFQ data has not been entered into a database.  
Subject Recruitment and Data Collection:

**Task IV Final Analysis, Report Writing, and Presentations (5 – 12 months)**

Data analysis and manuscript preparation.

Data analysis has commenced and some of the tables generated are shown in the appendix.

Present results at seminars.

A departmental seminar presentation has not been scheduled.

Communicate results to peer-reviewed journals and scientific meetings.

Manuscript preparation has not started as there is need to accrue more prostate cancer cases into the study and do compare cases and controls as stated in the objectives. However in a small pilot comparison, the fatty acid profile of these 12 West African migrants was compared to that of 12 Nigerians in their home country. Statistically significant differences in omega-3 and omega-6 fatty acids were noted in this limited sample size.

## **TECHNICAL AND UNEXPECTED DIFFICULTIES**

I realize that the African migrant is a unique minority population and that studying their health issues will not be easy because their statistics is embedded within that for African Americans. Also it is not possible to get residential information on any migrant population. The challenge is therefore to find recruitment strategies that will target migrants. African migrants will tend to self-exclude themselves from studies that are advertised for African-Americans. I had hoped that this study that was specifically and directly targeted would accrue participants much more quickly. This has not been the case for the following reasons:

1. African migrants sometimes worry about their information not being confidential especially with regards immigration and health insurance.
2. They also did not want to screen for a disease when they do not have health insurance or a means of dealing with a health diagnosis if identified.
3. Several of them work 2 jobs and at week-ends and job commitments make it impossible to keep a morning appointment for fasting blood draw.
4. Although they are told that the study will last 2-hours and that they will get transportation/parking incentive (\$15) they felt that this was not enough compensation as attendance will translate to one day absence from work and one day loss in wages. The PI offered \$20 incentive to stimulate more interest and offered an additional gift lunch bag to participants who promised to help recruit at least an additional participant.
5. Lack of accurate information about cancer treatment and cancer research was apparent meaning that more time and individual contact is necessary to inform and convince people to consider participation in cancer research/cancer screening. (Free diabetes and prostate cancer screening were both advertised as added incentives for participation in this study.)
6. Churches form a very good contact point and the PI had hoped that church leaders could be effective disseminators of study information. Church leaders are very busy and research matters did not appear as a priority. Besides church activities happen outside regular work hours. The PI will plan to conduct initial information and registration activities for Sunday mornings and other week day evenings when church groups meet for special church activities like prayer, bible or choir meetings. There is therefore need for research field assistants who will work on Saturdays and Sundays.
7. Religious groups such as churches were planned as the main point of contact for reaching this population. Churches tended to serve specific ethnic/racial groups and it was not easy to identify churches for Africans just from their names. Thus the yellow pages, and even the Shepherd's Guide (a directory of churches) was not useful in that sense. Churches were therefore identified by information from individuals, limiting the number contacted and the national spread of the study population.

8. Funds to recruit and hire research assistants/interviewers and a laboratory assistant/phlebotomist has not been secured. The task of data collection, sample collection and data entry will be better handled by them.
9. The dietary assessment using NUTRITIONIST VI Software has not been started. Experts who handle Dietary Assessment data are available at a cost, however there is a need to develop additional nutrient base for certain African ethnic foods that are not in the standard American nutrient database. Funds for this aspect needs to be sourced for.

#### **KEY ACCOMPLISHMENTS:**

1. This is one of the first studies, if not the only study, that has focused on African migrants.
2. A FFQ has been developed to capture up to 85% of food items consumed by Americans and by Africans.
3. Simple food models have been developed.
4. The PI has identified the Kennedy Krieger research laboratories for nutrient analysis and the Fred Hutchinson Cancer Research Center for future design of a FFQ questionnaire that can be analyzed by scanning.
5. Monthly prostate cancer screening is being offered to men in the Washington metropolitan area, and public service announcements are aired on selected radio and television channels monthly.
6. A listing of African associations and groups and contact with leaders has been initiated and will be maintained.
7. This minority community is now being made aware directly of the need to participate in health and research activities. Information about health research has been disseminated on:
  - a. Association web page, meetings and newsletters.
  - b. Radio interview
  - c. Television interview
8. Student volunteers (3) have been trained in recruiting and interviewing participants and in SPSS data entry.

The study has met most of the set objectives by:

1. Established partnership ties with the community.
2. Identified a cohort of 111 West African males.
3. Conducted free prostate cancer screening for the community.
4. Completed demographic and dietary assessment information for 55 men.
5. Collected and stored plasma, serum, cells, clot and urine samples for laboratory analysis.
6. The intent to recruit 50 prostate cancer cases and 100 age/zip code matched controls with normal PSA and DRE into the study was not met. There is need to develop a more efficient way of recruiting prostate cancer cases into the study.

## **REPORTABLE OUTCOME:**

1. Serum, plasma, clot and cell repository for 55 persons.
2. Database (demographic and epidemiologic information) for 55 persons and prostate cancer screening database for 56 additional persons. A database of laboratory results including lipids, essential fatty acids, Testosterone and Vitamin E analysis for 12 persons. This data base also includes Selenium and Vitamin C information for 6 persons only.
3. Applied for DOD idea development grant to continue with this study and adding the African American population as a comparison group.

## **CONCLUSION:**

A minority, understudied and most likely medically underserved population such as this requires more than one year for an initial pilot study. This grant has helped to initiate the study and has shown that it is feasible. Also this initial nutrient analysis already shows that there is certainly a difference between the migrants and their relations in the home country. It is therefore worthy of study to continue the study and the following should be considered as ways of improving participation.

1. Seek funding to expand the study population to include African-Americans such that comparison can be within and between the two sub-populations.
2. Increase the financial incentive for each participant to \$50 since the participants will be required to make at least two visits and will be donating 3 tubes of blood. This amount will partially compensate for time away from work, transport costs and inconveniences.
3. Serve a snack and drink after blood draw since participants have not had any breakfast and are hungry and restless during the lengthy dietary assessment interview.
4. Arrange for community outreach prostate education programs at churches to attract participation and then other health and study specific topics can be addressed such that the community can 'get something back' from this study.
5. Hire part-time recruiters from within the different sub-populations who will spend evenings and week-ends to recruit participants.
6. Distribute pens, cups or magnets bearing the study logo and recruitment center telephone number.
7. Family physicians are in a better position to refer cases to the study. By the time they get to the urologist the diagnosis has been concluded and the patients are more concerned with treatment plans rather than in research that does not bear direct benefits for their condition.
8. Additional incentive for cases may be worthwhile, such as contributing to the cost of biopsy especially for those without insurance, and arranging for referral to social workers for financial assistance for their treatment.

## RESULTS:

**Table 1. Sources Contacted to Recruit West African Migrants.**

Type of Contact	N
Urologists (DC,,MD.,VA.)	240
Individuals	193
West African Ethnic Associations	70
International Food Stores/Restaurants	55
Religious Groups (Churches etc.)	46
Embassies of Selected African Countries	12
African Newspaper/Newsletter	4
Health Fair	2
African Association Health Conference	1
African Radio Program Announcement	1
Radio Interview	1
Television Interview	1

### Analysis:

Of 111 participants recruited into the study, 69(62.2) are from Maryland, 36(32.4) from the District of Columbia and 3(2.7) from Virginia. 63(56.8) Africans responded to the study flyer, 56(50.5) to prostate cancer screening and 2(1.8) were identified from the Howard University Hospital cancer register. Flyers and study information was distributed to urologists in the area, African associations, food stores and embassies. (Table 1). Their ages ranged from 40 – 77 years with a mean of  $50.5 \pm 7.7$  years, excluding 6 men who were below 40 years. (Table 2)

PSA ranged from 0.1 ng/ml – 26.8 ng/dl. with 7(6.3) having abnormal PSA over 4 ng/ml. The 8(7.2) under 40 years had normal PSA less than 4.0 ng/ml (Table 2). 6(5.4) of these men have previously been diagnosed with prostate cancer. Among the 56 persons who came for screening only, PSA correlated with age,  $r = 0.3$  ( $p < 0.06$ ) and among those who completed the study the correlation was  $r = 0.4$  ( $p < 0.004$ ). PSA did not correlate with either weight or height in either group.

81(73.0) have had at least a rectal examination in the past, 17(21.0) with enlarged prostate and 2(2.5) with abnormal prostate on DRE. Of the 30(27.0) persons who have never had a rectal examination 4(7.1) of those who attended the screening program refused digital examination while 19(34.5) of those who completed dietary questionnaire are yet to schedule a rectal examination. Two of the participants with abnormal PSA did not indicate if they had a rectal examination with their own urologists/physician.

The following analysis is limited to the 53 persons who completed the study questionnaire. 6(10.9) did not complete most aspects of the questionnaire.

Their ages ranged from 40 – 71 with a mean of  $50.5 \pm 7.7$  years. 3(5.5) have lived in America for less than one year, 16(29.0) for 2 – 10 years, 30(54.6) for 20 years or longer.

Of the 53 persons who completed the study questionnaire, 27(50.9) are Nigerians, 13(24.5) Ghanaians, 4(7.5) from Cameroon, 4(7.5) other West Africans and 5(9.4) other Africans. 40(75.5) live in Maryland, 10(18.9) Washington DC and 3(5.7) Virginia. 13(24.5) left their home country between the ages of 18 – 24 years, 13(24.5) between 25 –34 years and 23(43.4) at 40 years or older. 27(50.9) completed over 16years of formal education with a college or graduate degree, 17(32.1) completed 13 – 16 years of education, 3(5.7) completed 12 years of education while 2(3.8) completed less than 12 years.

39(73.4) are married, 7(13.2) separated or divorced while 3(5.7) are single. ) One of the men has no children, 32(60.4) have 1-4 children, 14(26.4) have 5 or more children. 8(15.1) did not indicate the number of children they have. Annual family income of 23(43.4) was \$75,000 and more, for 12(22.6) it was \$35,000 - \$74,999, below \$35,000 8(15.1) and 10(18.9) did not disclose this information.

36(67.9) claimed never to have had a PSA testing, 2(3.8) admitted to their father having been diagnosed with enlarged prostate while another 2(3.8) admitted to a family history of prostate cancer, one in a brother and the other the father. Only 4(7.5) admitted having any urinary symptoms and none had a vasectomy.

Of the 20(37.7) who had used tobacco at one time, 11(20.8) have quit the habit, 8 of them for over 10 years. Only one participant smoked more than 20 cigarettes per day, one person smoked 10 and the rest smoked 5 or less. 16(29.1) do not drink alcohol, 26(49.1) did so on special occasions only, 7(13.2)) drank regularly and 4(7.5) did not state their drinking habit.

**Table 2      Age Distribution of West-African Migrants in the Study Population.**

Age-group (Yrs.)	Completed Study Protocol		Prostate Cancer Screening Only		Total		
	N	%	N	%	N	%	
< 40	5	7.3	3	5.4	8	7.2	
40 – 49	26	47.3	19	33.9	45	40.5	
50 – 59	16	25.5	15	13.5	31	27.9	
60 – 69	6	9.1	15	13.5	21	18.9	
>= 70	2	3.6	2	3.4	4	3.6	
Not Stated	0	7.3	2	3.4	2	1.9	
Total	N	55	100.0	56	100.0	111	100.0
	%		(49.5)		(50.5)		

**Table 3.****PSA Distribution by Age Group for West African Migrants.**

PSA (ng./ml.)	< 40	40 – 49	50 – 59	60 – 80	Not Stated	Total	
						N	%
< 0.1	-	-	-	1	-	1	0.9
0.1 – 2.4	7	36	25	19	2	89	80.2
2.5 – 3.9	-	3	2	-	-	5	4.5
4.0 – 9.9	-	2	1	2	-	5	4.5
>= 10	-	-	3	2	-	5	4.5
Not Recorded	1	3	1	1	-	6	5.4
Total %	8 (7.2)	44 (39.6)	32 (28.8)	25 (22.5)	2 (1.8)	111	100.0

**Table 4.****Comparison of Free Fatty Acid Profile of West African Migrants and Rural Nigerians:**

Fatty Acid	Mean (SD) Fatty acid (ug./ml.)		p-value
	West African Migrants	Nigerians	
Total	2318.22 (772.66) <i>h</i>	2096.11 (393.26)	ns
Total Saturated	714.87 (259.4)	752.45 (154.28)	ns
Total Omega-6	916.51 (207.03) <i>h</i>	586.51 (110.48)	0.000
Total Omega-3	130.03 (73.77)	142.42 (57.75)	ns
Myristic acid	15.55 (11.14)	21.20 (10.08)	ns
Palmitic acid	455.19 (181.84)	534.44 (116.77)	ns
Stearic acid	178.82 (60.86) <i>h</i>	152.91 (27.87)	ns
Oleic acid	398.65 (234.75)	460.23 (106.98)	ns
Palmitoleic acid	29.91 (16.61)	62.55 (32.10)	0.006
Linoleic acid	69.84 (173.71) <i>h</i>	435.30 (83.27)	0.001
Arachidonic acid	85.60 (49.72) <i>h</i>	99.14 (24.46)	0.000
Alpha linolenic acid	17.54 (17.29) <i>h</i>	5.36 (1.40)	0.033
Eicosapentaenoic acid	28.96 (30.34)	44.24 (25.01)	ns
Docosahexaenoic acid	67.17 (35.70)	74.33 (28.95)	ns
C24/C22	0.88 (0.13)	1.28 (0.13)	0.000
C26/C22	0.01 (0.005)	0.02 (0.006)	0.000

*h* : Fatty acids that are higher among West African Migrants.



ID. # \_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_

# WEST AFRICAN MIGRANTS STUDY

## Personal Information

Name: \_\_\_\_\_  
(Last) (First) (Initials)

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Home Phone: (\_\_\_\_) \_\_\_\_-\_\_\_\_ Work Phone: (\_\_\_\_) \_\_\_\_-\_\_\_\_

Date of Birth: (mm/dd/yy) \_\_\_/\_\_\_/\_\_\_ Age Last Birthday: \_\_\_ years

Country of Origin: \_\_\_\_\_ Place of Birth: \_\_\_\_\_

Please provide the names of two relatives or friends, not living in your household, who are likely to know how to contact you if we cannot contact you directly. (OPTIONAL)

Name: \_\_\_\_\_ Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
City State Zip Code

\_\_\_\_\_  
City State Zip Code

Work Phone: (\_\_\_\_) \_\_\_\_-\_\_\_\_

Work Phone: (\_\_\_\_) \_\_\_\_-\_\_\_\_

Or

Or

Home Phone: (\_\_\_\_) \_\_\_\_-\_\_\_\_

Home Phone: (\_\_\_\_) \_\_\_\_-\_\_\_\_

Relationship: \_\_\_\_\_

Relationship: \_\_\_\_\_

The next few questions about your background are important to help describe, in general terms, the men who are part of this study.

1. How many years have you been in the United States of America? \_\_\_\_\_ years
2. How many years have you lived here ( DC, MD, VA)? \_\_\_\_\_ years
3. How old were you when you left your home country? \_\_\_\_\_ years
4. How many other countries did you live in for at least one year. \_\_\_\_\_  
(Specify) \_\_\_\_\_
5. What is the highest grade/level of school you completed? \_\_\_\_\_
6. What is the highest grade/level of school you completed in your home country? \_\_\_\_\_
7. What is your current job status?
  - Not working.
  - Retired.
  - Employed (part-time)
  - Employed (full-time)
  - Disabled, unable to work.
  - Other (Specify) \_\_\_\_\_
8. What is your occupation? \_\_\_\_\_
9. Which of the statements below best describes your job? If you are not currently working, which statement best describes your past job, that is, the job you held the longest.
  - Managerial, Professional, Administrative
  - Technical, Sales, Administrative support
  - Service
  - Operators, Fabricators, Labourers
  - Other (Specify) \_\_\_\_\_
10. What is your current marital status?
  - Single, Never married.
  - Married
  - Divorced or Separated
  - Widowed.
  - Remarried
  - Living together in a marriage-like relationship.
11. How many children do you have? \_\_\_\_\_
12. How many people, all together, do your support financially? \_\_\_\_\_

13. What was the approximate total family income (before taxes) from all sources within your household in the last year? This information will be used for describing all the men in the study as a group. Please note that all information in this study will be kept in strict confidence.

- |   |  |
|---|--|
| <input type="radio"/> Less than \$ 10,000   | <input type="radio"/> \$50,000 - <\$74,999 |
| <input type="radio"/> \$ 10,000 - <\$24,999 | <input type="radio"/> \$75,000 - <\$99,999 |
| <input type="radio"/> \$25,000 - <\$34,999  | <input type="radio"/> More than \$100,000  |
| <input type="radio"/> \$35,000 - <\$49,999  | <input type="radio"/> No Response/Personal |
| <input type="radio"/> Don't know            |  |

14. Do you have a clinic, doctor, nurse or physician assistant who gives you your usual medical care?

- No  Yes  
(Go to No. 15.) ↓

14.1 What is the name, address and phone number of your clinic, doctor, nurse or physician assistant? (OPTIONAL)

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
City State Zip Code

Phone: (\_\_\_\_) \_\_\_\_-\_\_\_\_

14.2 When did you last visit this clinic or person? (Give your best guess) (mm/yy) \_\_\_\_/\_\_\_\_

15. Have you ever had a blood test for prostate cancer, called the 'prostate specific antigen (PSA)' test?

- No  Yes  
(Go to No.16.) ↓

15.1 How many times in your life time have you had that test? \_\_\_\_\_

15.2 When did you have the last test? State year. 19 \_\_\_\_

15.3 If your last test was done in the last 12 months, what is the full name and address of the clinic/doctor where it was done?

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
City State Zip Code

15.4 What was the result of the test? \_\_\_\_\_

16. Has your doctor ever performed 'Digital Rectal Examination' (DRE) on you?  
 No                       Yes  
 (Go to No. 17)              ↓  
 16.1 When did you last have a DRE? (mm/yy) \_\_\_/\_\_\_  
 16.2 What was the result of the test? \_\_\_\_\_  
 16.3 Was this test performed at the same time with the PSA test?  
 No                       Yes

17. How do you usually pay for your medical care?  
 Pre-Paid private Insurance (Like HMO)  
 Other private insurance (Like Blue Cross)  
 Medicare  
 Medicaid  
 Military or Veterans  
 No Insurance  
 Other (Explain) \_\_\_\_\_

18. Have you ever had any problems passing urine?  
 No                       Yes  
 (Go to No. 18)              ↓  
 18.1 When was this? Please give your best guess. (mm/yy) \_\_\_/\_\_\_  
 18.2 Describe the problem you had passing urine.  
 \_\_\_\_\_  
 18.3 What did you do about it?  
 \_\_\_\_\_

19. Have you ever been told that you have a Benign Enlargement of the Prostate? (BHP)  
 No                       Yes

20. Have you ever been diagnosed with prostate cancer?  
 No                       Yes

21. Have you ever had any prostate or testis biopsy, surgery or operation?  
 No                       Yes  
 (Go to No. 20)              ↓  
 21.1 Which surgery did you have? \_\_\_\_\_  
 21.2 When did you have the surgery? 19 \_\_\_ How old were you? \_\_\_  
 21.3 Why did you have the surgery? \_\_\_\_\_

22. Did you have a vasectomy?

No  Yes

(Go to No. 23)

↓

22.1 When did you have a vasectomy? 19\_\_

23. Has anyone in your family ever been diagnosed with enlarged prostate? (BHP)

No  Yes

(Go to No. 24)

↓

23.1 Who was diagnosed with BHP? \_\_\_\_\_

23.2 When was this? 19\_\_

23.3 How old was he? \_\_\_\_\_ years.

23.4 State the age at which any other family member was diagnosed with Benign Prostate Enlargement. \_\_\_\_\_

24. Has anyone in your family been diagnosed with cancer of the prostate?

No  Yes

(Go to No. 25)

↓

24.1 Who was diagnosed with cancer of the prostate?  
\_\_\_\_\_

24.2 When was this diagnosis? 19\_\_

24.3 How old was he at diagnosis? \_\_\_\_\_ years.

24.4 Give age at diagnosis for any other family member diagnosed with cancer of the prostate. \_\_\_\_\_

25. Please try and count, and give me a number for all your first degree male relations:  
(Father, Uncles, Brothers and Sons within the following age groups)

Relation:	Age Group					
	Alive			Died		
	<40	40-60	>60	<40	40-60	>60
Father's father						
Mother's father						
Father						
Brothers						
Sons						
Uncles						
Nephews						
All others						

**TOBACCO USE HISTORY:**

27. Have you ever used tobacco?  
 No                       Yes                       Refused

↓  
 What type of tobacco did you use?

- Chewing tobacco
- Sniffing tobacco
- Licking tobacco
- Pipe
- Cigars
- Cigarettes

26. How old were you when you started using tobacco in any form? \_\_\_\_\_ years

27. Please indicate the current (or past ) frequency of use for each form of tobacco.

Tobacco	Use Everyday	Use Some Days	Average Daily Quantity	Do Not Use At All .
Cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	_____ sticks	<input type="checkbox"/>
Cigars	<input type="checkbox"/>	<input type="checkbox"/>	_____ sticks	<input type="checkbox"/>
Pipe	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>
Chewing	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>
Sniffing	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>
Licking	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>

29. If you have stopped using tobacco please indicate how long ago.

29.1 How long ago since you last used smokeless tobacco? \_\_\_\_\_ months. Or \_\_\_\_\_ years.

29.2 How long ago since you last smoked a pipe or cigars? \_\_\_\_\_ months. Or \_\_\_\_\_ years.

29.3 How long ago since you last smoked cigarettes? \_\_\_\_\_ months. Or \_\_\_\_\_ years.

**ALCOHOL USE HISTORY:**

30. Do you drink any alcoholic beverage such as beer, wine, wine coolers, or liquor?  
 No             Yes, only at special occasions     Yes, Regularly             Refused

31. If regularly please state quantity and frequency per week for each type of alcohol. If you drink less than once a week, then state the frequency per month.

Type of alcohol	Quantity	Frequency
1 Beer	_____	_____/____
2 Wine	_____	_____/____
3 Wine Coolers	_____	_____/____
4 Liquor	_____	_____/____

32. A drink is 1 can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, or 1 cocktail or 1 shot of liquor. On the days when you drank, about how many drinks did you drink on the average?

\_\_\_ \_\_\_ No. of drinks       Don't know       Refused

33. Considering all types of alcoholic beverages, how many times during the past month did you have 5 or more drinks on an occasion?

\_\_\_ \_\_\_ No of times       Don't know       Refused

**PHYSICAL MEASUREMENT HISTORY:**

34. What were the following measurements around the ages shown below?  
(Please state if your entry at any age point is a guess)

Measurement	Age 20	30	40	50	60+	Presently
Height	_____	_____	_____	_____	_____	_____
Weight	_____	_____	_____	_____	_____	_____

35. Please try and recall your best guess for each clothing size at around the following ages .

Size	Age 20	30	40	50	60+	Presently
Shirt size	_____	_____	_____	_____	_____	_____
Trouser size	_____	_____	_____	_____	_____	_____

**PHYSICAL MEASUREMENTS.**

	First Reading	Second Reading		
Height	_____	_____	Chest	_____
Weight	_____	_____	Waist	_____
Mid-arm circumference	_____	_____	Hip	_____
Skinfold Measurements:			Fasting Blood Sugar	_____
Biceps:	_____	_____		_____
Triceps:	_____	_____		_____
Subscapular:	_____	_____		_____



ID# \_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_

# DIETARY ASSESSMENT

## DETAILED FOOD QUESTIONNAIRE

NAME: \_\_\_\_\_  
(Last) (First) (Initials)

These questions ask about the foods you ate during the LAST THREE (3) MONTHS.

1. Did you eat chicken or turkey during the last three months?

No (Go to Question 2.)  Yes  
↓

1.1 When you ate chicken or turkey, how often did you eat the skin?

- Almost always
- Often
- Sometimes
- Rarely
- Never

1.2 Did you usually choose ...

- Light meat (wings and breast)
- Dark meat (drum-stick / thigh)
- Both

2. Did you eat beef, pork, lamb or goat during the last three months?

No (Go to Question 3.)  Yes  
↓

2.1 When you ate beef, pork, lamb or goat, how often did you eat the fat?

- Almost always
- Often       Sometimes
- Rarely       Never

3. Did you eat any ground meat or hamburger during the last three months?

No (Go to Question 4.)  Yes  
↓

3.1 When you ate hamburger or other ground meat, was it usually ...

- Regular
- Lean
- Extra Lean
- Ground turkey
- Don't Know

4. Did you eat canned tuna (sardines) during the last three months?

No (Go to Question 5.)  Yes  
↓

4.1 When you ate canned tuna was it usually ....

- Water-packed     Oil-packed
- Either one
- Don't know

4.2 When you ate canned tuna how was it usually prepared? (Mark one or two.)

- Tuna, plain
- Tuna salad with myonnaise
- Tuna noodle casserole

5. Did you use/drink milk in the last three months?

No (Go to Question 6)

Yes  
↓

5.1 What type of milk or milk beverage did you drink?

- Whole milk
- 2% milk
- 1% milk
- Non-fat or skim milk
- Evaporated / Condensed
- Regular powdered milk
- Skim powdered milk
- Soy milk
- Don't know

5.2 What type of milk or cream(er) did you usually use on cereal?

- Whole milk
- 2% milk
- 1% milk
- Non-fat or skim milk
- Evaporated / Condensed
- Regular/Skim powdered
- Non-diary creamer
- Soy milk
- Don't know

5.3 What type of milk or cream(er) did you use in your tea/coffee?

- Whole milk
- 2% milk
- 1% milk
- Non-fat or skim milk
- Evaporated / Condensed
- Regular/Skim powdered
- Non-diary creamer
- Soy milk
- Don't know

6. Did you eat cold cereals during the last three months?

No (Go to Question 7)       Yes  
↓

6.1 When you ate cold cereals, what type did you usually eat? (Mark one or two).

- Granola cereals
- High-fiber or bran cereals, FiberOne, Raisin Bran.
- Whole grain cereals such as Cheerios, Shredded Wheat.
- Fortified cereals such as Total, Product 19.
- Cereals such as Corn Flakes, Frosted Flakes, Fruit loops.
- Oat meal, 'Corn Pap'

7. Did you eat squash, yam or plantain in the last three months?

No (Go to Question 8)       Yes  
↓

7.1 When you ate squash, yam, plantain or potato how often were they fried?

- Almost always
- Often
- Sometimes
- Rarely
- Never

8. What kinds of fat did you usually use to deep/pan fry or saute foods? (Mark one or two.)

- Stick margarine
  - Tub margarine
  - Butter
  - Shortening (Crisco, lard, bacon fat, salt pork, ham hock)
  - Olive oil or Canola oil
  - Specify other vegetable oils (corn, peanut, sunflower oil)
- 
- Non-stick spray (Pam)
  - Palm oil
  - Do not fry

9. Do you usually add **fat, stew or sauce** when cooking **beans and vegetables**? (circle as applicable)

- No (Go to Question 10)     Yes  
↓

9.1 Specify the type of fat you add.

- Stick margarine  
 Tub margarine  
 Butter  
 Shortening (Crisco, lard, bacon fat, salt pork, ham hock)  
 Olive oil or Canola oil  
 Specify other vegetable oils (corn, peanut, sunflower oil)  
\_\_\_\_\_  
 Non-stick spray (Pam)  
 Palm oil

10. Do you usually add **fat, stew, or sauce** to **beans and vegetables** after cooking? (circle as applicable)

- No (Go to Question 11)     Yes  
↓

10.1 Specify the type of fat you add.

- Stick margarine  
 Tub margarine  
 Butter  
 Shortening (Crisco, lard, bacon fat, salt pork, ham hock)  
 Olive oil or Canola oil  
 Specify other vegetable oils (corn, peanut, sunflower oil)  
\_\_\_\_\_  
 Non-stick spray (Pam)  
 Palm oil

11. What kind of fat do you usually use on **bread, muffins, tortillas, rolls, bagels**?

Specify: \_\_\_\_\_

12. What types of ice cream/yogurt did you eat in the last three months?

- Regular  
 Low fat  
 No fat  
 None

13. What type of salad dressing did you usually use?

- Regular  
 Low-fat (diet)  
 Fat free (no fat)  
 Did not use dressing

14. Do you use myonnaise on sandwiches and salads?

- No (Go to Question 15)     Yes  
↓

14.1 What type of myonnaise did you usually use?

- Regular  
 Low-fat (diet)  
 Fat free (no fat)  
 Did not use dressing

15. Did you eat cookies (biscuits) during the last three months?

- No (Go to Question 16)     Yes  
↓

15.1 How often were they graham crackers, vanilla waffers, fig bars, cabin biscuit, or special low-fat or no-fat cookies?

- Almost always  
 Often  
 Sometimes  
 Rarely  
 Never

16. Did you eat cakes or other pasteries during the last three months?

- No (Go to Question 17)     Yes  
↓

16.1 How often were they angel cakes, sponge cakes, or special low-fat or no-fat cakes or pasteries?

- Almost always  
 Often  
 Sometimes  
 Rarely  
 Never

17. Did you eat popcorn in the past three months?

- No (Go to Question 18)  Yes  
↓

17.1 What type of popcorn did you usually eat?

- Popped in oil, at the movies  
 Regular microwave  
 Air-popped or special "lite" microwave  
 Do not eat popcorn.

17.2 When you ate popcorn how often did you add butter, margarine, groundnut?

- Almost always  
 Often  
 Sometimes  
 Rarely  
 Never

18. Did you eat corn flour in any of its forms in the last three months?

- No (Go to Question 19.)  Yes  
↓

18.1 In what form did you eat corn flour or corn meal?

- Pudding (Akamu)  
 Kenki or Agidi  
 Corn bread  
 Specify \_\_\_\_\_

18.2 Specify the type of fat, stew or soup you usually ate with it.

Specify \_\_\_\_\_

19. Did you eat corn in the last three months?

- No (Go to Question 20)  Yes  
↓

19.1 In what form was the corn you ate? (Excluding popcorn)

- Boiled corn-on-the-cub  
 Roasted corn-on-the-cub  
 Canned sweet corn  
 Ekusu (corn pudding)

19.2 Indicate how you ate boiled or cooked corn.

- Plain  
 Peanut/Coconut  
 Margarine / Butter

20. Did you eat rice in the last three months?

- No (Go to Question 21.)  Yes  
↓

20.1 In what form did you eat the rice?

- Boiled with margarine/butter  
 Boiled with \_\_\_\_\_ stew  
 Fried rice  
 Jollof rice  
 Chinese fried rice

21. Did you eat spaghetti, macaroni (pasta) in the last three months?

- No (Go to Question 22.)  Yes  
↓

21.1 In what form did you eat the pasta?

- Boiled + margarine/butter  
 Boiled + \_\_\_\_\_ stew/sauce  
 Boiled with cheese  
 Lasagna  
 Pasta salad

22. Did you eat a hamburger or sandwich in the last three months?

- No (Go to Question 23.)  Yes  
↓

22.1 Which of the following did you usually have on and with your hamburger or sandwich?

- Cheese, mayonnaise, mustard  
 French fries  
 Tomato, Lettuce, Pickle  
 Specify all others

23. When you ate chicken, fish, shrimps etc, were they usually fried

- Fried in batter (crust)  
 Fried plain  
 Not fried

Date: \_\_\_/\_\_\_/\_\_\_

ID # \_\_\_\_\_

## 24-HOUR DIETARY RECALL

Name: \_\_\_\_\_  
(Last) (First) (Initials)

Age: \_\_\_\_\_ Sex: \_\_\_\_\_

Please record or tell me everything you ate or drank, all day yesterday. Preparation methods include BOILED, BAKED, DEEP OR PAN FRIED, ROASTED, STEAMED, GRILLED, POUNDED, STEWED, MIXED ETC.

1.

BREAKFAST FOODS EATEN	AMOUNT	PREPARATION

2.

LUNCH FOODS EATEN	AMOUNT	PREPARATION

3.

DINNER FOODS EATEN	AMOUNT	PREPARATION

AMOUNTS: USE NUMBER, TEACUP, SERVING SPOON, TABLESPOON, TEASPOON, MUG, BOTTLE etc.

ID # \_\_\_\_\_

24-HOUR DIETARY RECALL

4. Did you eat or drink anything else between these meals? Remember to record fruits, carrots, chips, corn, pop-corn, nuts, biscuits, cookies, cakes, drinks, any other snacks.

NO       YES



Please record or tell me everything you ate or drank between meals yesterday.

5. Between BREAKFAST and LUNCH

FOOD EATEN	AMOUNT	PREPARATION

6. Between LUNCH and DINNER

FOOD EATEN	AMOUNT	PREPARATION

7. Between DINNER and BEDTIME

FOOD EATEN	AMOUNT	PREPARATION

INTERVIEWER: \_\_\_\_\_

## FOOD FREQUENCY QUESTIONNAIRE

ID# \_\_\_\_\_

Throughout this interview I will ask you how often you ate certain foods in the past year. Please tell me the number of times you ate the mentioned item in a day, a week, a month, a year or not all. You also need to tell me the usually quality or serving size you ate.

FOOD	NEVER	FEW TIMES A YEAR	1-2 TIMES A MONTH	1-2 TIMES A WEEK	3-4 TIMES A WEEK	5-7 TIMES A WEEK	2 OR MORE TIMES A DAY	QUANTITY OR PORTION SIZE EACH TIME
	NIL NO	RARE	OCCAS SIONS	SOME TIMES	OTHER DAY	DAILY	MANY TIMES	
Chicken, Hen Turkey, Smoked T								1/16 1/8 1/2 1/4
Beef, Roast Lamb, Goat Pork, Ham, Smoked pork Bush meat								A B C
Skin, Feet Kidney, Liver, Gizzard Tripe, Chitlings								#
Minced meat (beef meatloaf, m balls Ground turkey, Picadillo								# balls #slices
Sausage, Hotdog, Bacon Eggs								#
Lunch meat ham Turkey lunch mt Bologna, Salami, Pepperoni								# slices
Canned meats Luncheon meat Corned beef Tuna, Sardines Canned Fish								1/8 1/4 1/2 1 # pieces
Dark f, White fish, Dry f, Smoked fish Stock fish								#pieces/fillet
Shrimp, Lobster Crab Snail Scallop, Oysters Periwinkle								#
Frozen Lunch/Dinner								specify
Gravies (meat drippings) White sauce								#serving spoon

FOOD	NEVER	FEW TIMES A YEAR	1-2 TIMES A MONTH	1-2 TIMES A WEEK	3-4 TIMES A WEEK	5-7 TIMES A WEEK	2 OR MORE TIMES A DAY	QUANTITY OR PORTION SIZE EACH TIME
	NIL NO	RARE	OCCAS SIONS	SOME TIMES	OTHER DAY	DAILY	MANY TIMES	
Rice Rice Flour								
Spagetti, Pasta Macaroni, Noddles Semolina, Farina								
Corn Bread Ekusu Agidi, Kenki Corn flour (Pap) Millet Corn Boiled Corn Roasted								
Yam Pounded Yam Yam Elubo								
Plantain boil (G/R) Plantain roast (G/R) Plantain Elubo								#
Gari Cassava boiled Fufu ('Santana') Starch Casava/Ptt Cassava Elubo								
Irish Potato Baked French Fries Swt Potato (yams) Cocoyam								# S/M/L
White Bread, Rolls Wheat/Rye bread								# / slices
Pizza Ham/Cheeseburger (Home/ Fast food)								# sl
Pita, Soft taco Enchilada Ethiopean bread								
H Taco, Corn Chip Potato Chips Plantain Chips Plantain ripe fried Vegetables								# small pkt.
CEREAL specify - - -								

FOOD	NEVER	FEW TIMES A YEAR	1-2 TIMES A MONTH	1-2 TIMES A WEEK	3-4 TIMES A WEEK	5-7 TIMES A WEEK	2 OR MORE TIMES A DAY	QUANTITY OR PORTION SIZE EACH TIME
	NIL NO	RARE	OCCAS SIONS	SOME TIMES	OTHER DAY	DAILY	MANY TIMES	
Green/String beans Green peas Split peas								# serving spoon
Baked beans Chili beans Black-eye beans Lima beans								# serving spoon
Brussels sprouts Lentil Turnips Mushrooms								# serving spoon
Hominy Carrots Cucumber								# baby/whole # sl
*Cooked leaves Collard, Spinach Mustard Pumpkin / bitter Cocoyam / Sweet Egusi stew Ogolo stew Okra Stew								# kitchen spoon
Squash Sum/Wintr Zucchini, Nopales,								#sl
Acorn, Butternut Pumpkin								
Mixed Veg. salad Lettuce salad Coleslaw								# serving spoon
Onion (raw/cooked) Spring onion Leek, Celery								
Broccoli Cabbage Cauliflower Sauerkraut								# serving spoon
Tofu Veggie burger Vegetarian Special Vegetarian Special								# pieces
Bell Pepper G,Y,R (Raw / Cooked) Chili / Hot (thin/round pepper Jalopeno,								1/8 1/4 1/2 1

FOOD	NEVER	FEW TIMES A YEAR	1-2 TIMES A MONTH	1-2 TIMES A WEEK	3-4 TIMES A WEEK	5-7 TIMES A WEEK	2 OR MORE TIMES A DAY	QUANTITY OR PORTION SIZE EACH TIME
	NIL NO	RARE	OCCAS SIONS	SOME TIMES	OTHER DAY	DAILY	MANY TIMES	
Apples, Pears Apricots, Peaches Nectarines, Plums								#
Bananas Kiwi, Guava Avocado pear Little pear								#
Cantalope, Orange melon Honeydew Papaya, Mango								1/16 1/8 1/4 1/2
Strawberry Grapes, Berries Cherry								#
Oranges, Tangerines Grapefruits Lemon								
Watermelon Red melon Pineapple								1/16 1/8 1/4 1/2
Canned fruits Fruit cocktail/salad Applesauce								# serving spoon
Tomato Juice, Tomato Ketchup Tomato Stw/Sauce Salsa, Sal. picante Fresh Tomato								Oz glass Tbs  # sl / cherry
Groundnuts Cashew nuts Sunflower Pumpkin seeds Walnut Pecans								# serving spoon
Spices - - -								
Vitamins /Supplt. - - - -								# Tablets a day/wk

FOOD	NEVER	FEW TIMES A YEAR	1-2 TIMES A MONTH	1-2 TIMES A WEEK	3-4 TIMES A WEEK	5-7 TIMES A WEEK	2 OR MORE TIMES A DAY	QUANTITY OR PORTION SIZE EACH TIME
	NIL NO	RARE	OCCAS SIONS	SOME TIMES	OTHER DAY	DAILY	MANY TIMES	
Tea Regular/Decaf Coffee Regular/ Decaf Chocolate Drink Chocolate Shake								# teacup/mug
Milk Ice cream Yogurt Cheese								# oz /glass
Sodas - - - -								Oz/can/bottle
Fruit Juice - - - -								Oz/can/bottle
Sweets, Candy Chocolate - - -								
Wines - -								#Wine glass
Beer - -								#can
Spirits - -								# shots
Cakes								# sl
Cookies								# S/L
Dessert - - -								# sl

CONSENT FOR INVESTIGATIVE PROCEDURES  
HOWARD UNIVERSITY  
WASHINGTON, DC. 20059

CONSENT FORM FOR HUMAN SUBJECTS  
(CASES)

SUBJECT'S NAME (Please print or type): \_\_\_\_\_  
(Last) (First) (Initial)

PROJECT TITLE: The Role of Dietary Fat and Antioxidants in Prostate Cancer Risk Among West African Migrants in America:  
A Pilot Case-Control Study

PROJECT DIRECTORS: Flora A.M. Ukoli, MB.BS.,MPH, Lucile L. Adams-Campbell, Ph.D., Chiledum Ahaghotu, MD., Tanya D. Agurs-Collins, Ph.D., Isaac J. Powell, MD.

I understand that the following tests and procedures for this research project will be completed at the Howard University Cancer Center at no cost to me and will only take one visit that will last 90 minutes.

Tests and Procedures to be Performed.

- a. Collection of information on demographic, family, migratory, mobility, diet and growth history, height, weight, waist and hip measurements by a trained interviewer.
- b. Collection of 50ml (10 teaspoonfuls) of venous blood by a certified nurse or phlebotomist to measure prostate specific antigen (PSA, blood test for prostate cancer), fatty acids and lipids, vitamins E and C, selenium and testosterone.
- c. Collection of 5ml of urine.

**Purpose of the Study:** I understand that the purpose of this research is to study the dietary styles or changes of West African Migrants to America that may increase their risk of, or protect them from prostate cancer. I understand that I will have to give information about the items and serving sizes of my present diet and in my home country. My height, weight, waist and hip will be measured. Approximately 10 teaspoonful of my blood will be drawn from my vein at the clinic visit. The questionnaires I will complete will take approximately one hour.

I give permission to obtain medical information and pathology reports that are relevant to prostate cancer from my medical records. I permit the draw of 10 teaspoonfuls of blood, for the said tests to be conducted on the blood sample and for prostate tissue specimen to be stored for subsequent research.

**Risks/Discomforts:** I understand that participation will not subject me to any physical risk other than that of a blood draw by a certified nurse or technician. Sometimes there may be slight bleeding under the skin where the needle was inserted for the blood draw and this bruise will clear within a few days.

Initials: \_\_\_\_\_  
(Participant) (Witness) (Principal Investigator)

...../2

**Benefits:** While there might be no direct benefit to me for participating in this study I realize that the results of this study will provide some information about dietary risks or protection of West African or American diets. I understand that this will be useful in developing strategies for the prevention or spread of prostate cancer in my community in particular and the world in general.

**Alternative Participation:** I could visit my doctor, clinic, nutritionist, or call the American Cancer Society for information on prostate cancer.

**Conditions of Participation:** Participation in this study is voluntary. If my questions now or at any time are not answered to my satisfaction, I can speak with the Principal Investigator Flora A.Ukoli, MB.BS, MPH, at 202-806-9259, or Chiledum Ahaghotu, MD, at 202-865-1314. I may withdraw from the project at any time. I understand that refusal to participate or withdrawal from the study will not influence my future medical care by the staff of Howard University Hospital, my physician or my urologist.

**Confidentiality:** You have promised to safeguard every information I provide, and a coded identification will be used instead of my name on any computerized files. The records from this study will be kept confidential and will not be given to anyone who is not helping on the study unless I agree to release the records. All completed interviews and surveys will be under lock in a separate set of files when not in use by project staff. The Institutional Review Board and representatives of the U.S. Army Medical and Material Command are eligible to review research records as a part of their responsibility to protect human subjects in research. My personal identity will be treated as confidential and will not appear in any computer database or on any published results.

**Injury:** I understand that in the event of physical or other injury resulting from the research tests or procedures, medical treatment will be provided at no cost to me, but that there will be no financial compensation.

I am free to call the Office of the Executive Secretary of Howard University Institutional Review Board at 202-806-7818 if I have questions I will like to discuss with someone other than the investigators on this project.

I acknowledge that I have read through and received a personal copy of this consent form.

**PARTICIPANT'S NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**SIGNATURE:** \_\_\_\_\_

**WITNESS TO CONSENT PROCEDURE:** \_\_\_\_\_  
(Name) (Signature)

**SIGNATURE OF PRINCIPAL INVESTIGATOR** \_\_\_\_\_

**DATE:** \_\_\_\_\_

CONSENT FOR INVESTIGATIVE PROCEDURES  
HOWARD UNIVERSITY  
WASHINGTON, DC. 20059

**CONSENT FORM FOR DONATION  
(CASES)**

SUBJECT'S NAME (Please print or type): \_\_\_\_\_  
(Last) (First) (Initial)

PROJECT TITLE: The Role of Dietary Fat and Antioxidants in Prostate Cancer Risk Among West African Migrants in America: A Pilot Case-Control Study

PROJECT DIRECTORS: Flora A.M. Ukoli, MB.BS.,MPH, Lucile L. Adams-Campbell, Ph.D., Chiledum Ahaghotu, MD., Tanya D. Agurs-Collins, Ph.D., Isaac J. Powell, MD.

I understand that there is a possibility that the blood sample and prostate specimen I provide under this study may also be used in other research studies and could potentially have commercial applicability. I voluntarily and freely donate all blood and urine samples for this study, and all prostate tissue collected at biopsy and surgery this day to the Howard University Cancer Center and hereby relinquish all right, title, and interest to the said items. I understand that the blood and urine samples and prostate specimens will be used for this study and will be stored for use in future studies. I understand that the stored samples will not contain any personal identifiers.

**PARTICIPANTS SIGNATURE:** \_\_\_\_\_

**WITNESS TO CONSENT PROCEDURE:** \_\_\_\_\_

**SIGNATURE OF PRINCIPAL INVESTIGATOR:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

CONSENT FOR INVESTIGATIVE PROCEDURES  
HOWARD UNIVERSITY  
WASHINGTON, DC. 20059

CONSENT FORM FOR HUMAN SUBJECTS  
(CONTROLS)

SUBJECT'S NAME (Please print or type): \_\_\_\_\_  
(Last) (First) (Initial)

PROJECT TITLE: The Role of Dietary Fat and Antioxidants in Prostate Cancer Risk Among West African Migrants in America: A Pilot Case-Control Study.

PROJECT DIRECTORS: Flora A.M. Ukoli, MB.BS.,MPH, Lucile L. Adams-Campbell, Ph.D., Chiledum Ahaghotu, MD., Tanya D. Agurs-Collins, Ph.D., Isaac J. Powell, MD.

I understand that I will require to register as a potential participant in this study. My visit to the Howard University Cancer Center will last about 90 minutes. If I am not initially selected as a study control this visit for only prostate cancer screening will last about 30 minutes. If I am subsequently found to be eligible as a control I will be invited for a second visit that will last an hour to complete detailed dietary questionnaires. I understand the following tests and procedures for the project will be at no cost to me.

Tests and Procedures to be Performed.

- a. Undergo physical examination by a urologist that includes a digital rectal examination (DRE).
- b. Collection of 50ml (10 teaspoonfuls) of venous blood by a certified nurse or phlebotomist to measure prostate specific antigen (PSA, blood test for prostate cancer), fatty acids and lipids, vitamins E and C, selenium and testosterone.
- c. Collection of information on demographic, family, migratory, mobility, diet and growth history, height, weight, waist and hip measurements by a trained interviewer.
- d. Collection of 5ml. of urine.

**Purpose of the Study:** I understand that the purpose of this research is to study the dietary styles or changes of West African Migrants to America that may increase their risk of, or protect them from prostate cancer. I understand that I will have to give information about the items and serving sizes of my present diet and in my home country. My height, weight, waist and hip will be measured. Approximately 6 teaspoonful of my blood will be drawn from my vein at the first clinic visit. The questionnaire I will complete will take approximately one hour. I understand that at the screening program I will have a physical examination that will include a digital rectal examination (DRE).

I give permission to obtain medical information and pathology reports from my medical records. I also permit the draw of 10 teaspoonfuls of blood and for the said tests to be conducted on the specimen.

**Risks/Discomforts:** I understand that participation will not subject me to any physical risk other than that of a blood draw by a certified nurse or technician and a DRE by a urologist. Sometimes there may be slight bleeding under the skin where the needle was inserted for the blood draw and this bruise will clear in a few days. The discomfort of a DRE is only at the time of the examination and will last no more than a few minutes. A positive PSA or DRE test could cause emotional upset and anxiety. If this should be the case I shall be referred to Dr. C. Ahaghotu or my primary care physician for follow-up and treatment.

Initials: \_\_\_\_\_  
(Participant) (Witness) (Principal Investigator) ...../2  
Ukoli, Flora A. M.

**Benefits:** One direct benefit to me for participating is the chance of early detection of prostate enlargement or cancer. I also realize that the results of this study will provide some information about dietary risks or protection of West African or American diets, and this will be useful in developing strategies for the prevention or spread of prostate cancer.

**Alternative Participation:** I could visit my doctor, clinic, nutritionist, or call the American Cancer Society for information on prostate cancer.

**Conditions of Participation:** Participation in this study is voluntary. If my questions now or at any time are not answered to my satisfaction, I can speak with the Principal Investigator Flora A.Ukoli, MB.BS, MPH, at 202-806-9259, or Chiledum Ahaghotu, MD, at 202-865-1314. I may withdraw from the project at any time. I understand that refusal to participate or withdrawal from the study will not influence my future medical care by the staff of Howard University Hospital.

**Confidentiality:** You have promised to safeguard every information I provide, and a coded identification will be used instead of my name on any computerized files. The records from this study will be kept confidential and will not be given to anyone who is not helping on the study unless I agree to release the records. All completed interviews and surveys will be under lock in a separate set of files when not in use by project staff. The Institutional Review Board and representatives of the U.S. Army Medical Research and Material Command are eligible to review research records as a part of their responsibility to protect human subjects in research. My personal identity will be treated as confidential and will not appear in any computer database or on any published results.

**Injury:** I understand that in the event of physical or other injury resulting from the research tests or procedures, medical treatment will be provided at no cost, but that there will be no financial compensation.

I am free to call the Office of the Executive Secretary of Howard University Institutional Review Board at 202-806-7818 if I have questions I will like to discuss with someone other than the investigators on this project.

I acknowledge that I have read and received a personal copy of this consent form.

**PARTICIPANT'S NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**SIGNATURE:** \_\_\_\_\_

**WITNESS TO CONSENT PROCEDURE:** \_\_\_\_\_  
(Name) (Signature)

**SIGNATURE OF PRINCIPAL INVESTIGATOR** \_\_\_\_\_

**DATE:** \_\_\_\_\_

CONSENT FOR INVESTIGATIVE PROCEDURES  
HOWARD UNIVERSITY  
WASHINGTON, DC. 20059

**CONSENT FORM FOR DONATION  
(CONTROLS)**

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Isaac J. Powell, MD.

I understand that there is a possibility that the blood sample I am providing under this study may also be used in other research studies and could potentially have commercial applicability. I voluntarily and freely donate all blood and urine samples drawn this day to the Howard University Cancer Center and hereby relinquish all right, title, and interest to the said items. I understand that the blood and urine samples will be used for this study and will be stored for use in future studies. I understand that the stored samples will not contain any personal identifiers.

**PARTICIPANTS SIGNATURE:** \_\_\_\_\_

**WITNESS TO CONSENT PROCEDURE:** \_\_\_\_\_

**SIGNATURE OF PRINCIPAL INVESTIGATOR:** \_\_\_\_\_

**DATE:** \_\_\_\_\_